

# Supplement to INFORMATION LETTER

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## FDA REGULATION UNDER FOOD ADDITIVE LAW

The Food and Drug Administration published in the Federal Register of January 19 a regulation listing substances that are generally recognized as safe within the meaning of the 1958 Food Additives Amendment to the Food and Drug Act. This is the second such list issued by FDA.

Pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 409, 701, 82 Stat. 1055, 72 Stat. 1785; 21 U.S.C. 348, 371) and delegated to the Commissioner of Food and Drugs by the Secretary (23 F.R. 9800), and after having considered all comments on the proposed order published in the Federal Register of April 21, 1959 (24 F.R. 3055), containing a list of spices, seasonings, essential oils, oleoresins, and natural extractives generally recognized as safe within the meaning of section 409 of the act, the Commissioner has concluded that the substances in that list, with the exception of cinchona bark (red), cinchona bark (yellow), orris root, orris (concrete, liquid), quinine, wintergreen, and

methyl salicylate are generally recognized as safe. The failure to include these substances in the list published in this order does not indicate that these substances as they are used for flavoring are not safe. However, it is concluded that in the case of the first five there is not a general recognition of their safety without adequate restrictions being placed upon their use as flavoring agents, through the promulgation of appropriate regulations. In the case of methyl salicylate and wintergreen, it was decided to delay any determination on the question of general recognition of safety pending the completion of pharmacological studies of methyl salicylate. These studies have been underway for some time and are expected to be completed by January 1, 1961.

(e) Spices, seasonings, essential oils, oleoresins, and natural extractives that are generally recognized as safe for

their intended use, within the meaning of section 409 of the act, are as follows:

(1) SPICES AND OTHER NATURAL SEASONINGS AND FLAVORINGS (LEAVES, ROOTS, BARKS, BERRIES, ETC.)

Common name	Botanical name of plant source
Allspice .....	<i>Pimenta officinalis</i> Lindl.
Anise .....	<i>Pimpinella anisum</i> L.
Anise, star .....	<i>Illicium verum</i> Hook. f.
Basil, sweet .....	<i>Ocimum basilicum</i> L.
Basil, bush .....	<i>Ocimum minimum</i> L.
Bay .....	<i>Laurus nobilis</i> L.
Calendula .....	<i>Calendula officinalis</i> L.
Capers .....	<i>Capparis spinosa</i> L.
Capicum .....	<i>Capicum frutescens</i> L. or <i>Capicum annuum</i> L.
Caraway .....	<i>Carum carvi</i> L.
Caraway, black (black cumin) .....	<i>Nigella sativa</i> L.
Cardamom (cardamon) .....	<i>Elettaria cardamomum</i> Maton.
Cassia, Chinese .....	<i>Cinnamomum cassia</i> Blume.
Cassia, Padang or Batavia .....	<i>Cinnamomum burmanni</i> Blume.
Cassia, Saigon .....	<i>Cinnamomum loureirii</i> Nees.
Cayenne pepper .....	<i>Capicum frutescens</i> L. or <i>Capicum annuum</i> L.
Celery seed .....	<i>Apium graveolens</i> L.
Chives .....	<i>Allium schoenoprasum</i> L.
Cinnamon, Ceylon .....	<i>Cinnamomum zeylanicum</i> Nees.
Cinnamon, Chinese .....	<i>Cinnamomum cassia</i> Blume.
Cinnamon, Saigon .....	<i>Cinnamomum loureirii</i> Nees.
Clary (clary sage) .....	<i>Salvia sclarea</i> L.
Cloves .....	<i>Eugenia caryophyllata</i> Thunb.
Coriander .....	<i>Coriandrum sativum</i> L.
Cumin (cumin) .....	<i>Cuminum cyminum</i> L.
Cumin, black (black caraway) .....	<i>Nigella sativa</i> L.
Dill .....	<i>Anethum graveolens</i> L.
Fennel, common .....	<i>Foeniculum vulgare</i> Mill.
Fennel, sweet (finocchio, Florence fennel) .....	<i>Foeniculum vulgare</i> Mill. var. <i>dulce</i> (DC.) Alef.
Fenugreek .....	<i>Trigonella foenum-graecum</i> L.
Garlic .....	<i>Allium sativum</i> L.
Ginger .....	<i>Zingiber officinale</i> Rosc.
Glycyrrhiza .....	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Grains of paradise .....	<i>Amomum melegueta</i> Rosc.
Horseradish .....	<i>Armoracia lapathifolia</i> Gilib.
Lavender .....	<i>Lavandula officinalis</i> Chaix.
Licorice .....	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Mace .....	<i>Myristica fragrans</i> Houtt.
Marigold, pot. .....	<i>Calendula officinalis</i> L.
Marjoram, pot. .....	<i>Majorana onites</i> (L.) Benth.
Marjoram, sweet .....	<i>Majorana hortensis</i> Moench.
Mustard, black or brown .....	<i>Brassica nigra</i> (L.) Koch.
Mustard, brown .....	<i>Brassica juncea</i> (L.) Coss.
Mustard, white or yellow .....	<i>Brassica alba</i> (L.) Boiss.
Nutmeg .....	<i>Myristica fragrans</i> Houtt.
Oregano (oregano, Mexican oregano, Mexican sage, origan) .....	<i>Lippia</i> spp.
Paprika .....	<i>Capicum annuum</i> L.
Parsley .....	<i>Petroselinum crispum</i> (Mill.) Manaf.
Pepper, black .....	<i>Piper nigrum</i> L.
Pepper, cayenne .....	<i>Capicum frutescens</i> L. or <i>Capicum annuum</i> L.
Pepper, red .....	Do.
Pepper, white .....	<i>Piper nigrum</i> L.
Peppermint .....	<i>Mentha piperita</i> L.
Poppy seed .....	<i>Papaver somniferum</i> L.
Pot marigold .....	<i>Calendula officinalis</i> L.
Pot marjoram .....	<i>Majorana onites</i> (L.) Benth.
Rosemary .....	<i>Rosmarinus officinalis</i> L.
Rue .....	<i>Ruta graveolens</i> L.
Saffron .....	<i>Crocus sativus</i> L.
Sage .....	<i>Salvia officinalis</i> L.
Savory, summer .....	<i>Satureia hortensis</i> L. ( <i>Satureja</i> ).
Savory, winter .....	<i>Satureia montana</i> L. ( <i>Satureja</i> ).
Sesame .....	<i>Sesamum indicum</i> L.
Spearmint .....	<i>Mentha spicata</i> L.
Star anise .....	<i>Illicium verum</i> Hook. f.
Tarragon .....	<i>Artemisia dracunculus</i> L.
Thyme .....	<i>Thymus vulgaris</i> L.
Turmeric .....	<i>Curcuma longa</i> L.
Vanilla .....	<i>Vanilla planifolia</i> Andr. or <i>Vanilla tahitensis</i> J. W. Moore
Zedoary .....	<i>Curcuma zedoaria</i> Rosc.

(2) ESSENTIAL OILS, OLEORESINS (SOLVENT-FREE), AND NATURAL EXTRACTIVES (INCLUDING DISTILLATES)

Common name	Botanical name of plant source
Allspice.....	Pimenta officinalis Lindl.
Almond, bitter (free from prussic acid).....	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Angelica root.....	Angelica archangelica L.
Angelica seed.....	Do.
Angelica stem.....	Do.
Angostura (cusparia bark).....	Galipea officinalis Hancock.
Anise.....	Pimpinella anisum L.
Asafoetida.....	Ferula asa-foetida L. and related spp. of Ferula.
Balsam of Peru.....	Myroxylon pereirae Klotzsch.
Basil.....	Ocimum basilicum L.
Bay leaves.....	Laurus nobilis L.
Bay (myrcia oil).....	Pimenta racemosa (Mill.) J. W. Moore.
Bitter almond (free from prussic acid).....	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Bois de rose.....	Aniba roseodora Ducke.
Cananga.....	Cananga odorata Hook. f. and Thoms.
Capsicum.....	Capsicum frutescens L. and Capsicum annum L.
Caraway.....	Carum carvi L.
Cardamon seed (cardamon).....	Elettaria cardamomum Maton.
Carob bean.....	Ceratonia siliqua L.
Cascarilla bark.....	Ocotea eluteria Benn.
Cassia bark, Chinese.....	Cinnamomum cassia Blume.
Cassia bark, Padang or Batavia.....	Cinnamomum burmanni Blume.
Cassia bark, Saigon.....	Cinnamomum loureirii Nees.
Celery seed.....	Apium graveolens L.
Chamomile flowers, Hungarian (camomile).....	Matricaria chamomilla L.
Chamomile flowers, Roman or English (camomile).....	Anthemis nobilis L.
Cherry, wild, bark.....	Prunus serotina Ehrh.
Chicory.....	Chicorium intybus L.
Cinnamon bark, Ceylon.....	Cinnamomum zeylanicum Nees.
Cinnamon bark, Chinese.....	Cinnamomum cassia Blume.
Cinnamon bark, Saigon.....	Cinnamomum loureirii Nees.
Cinnamon leaf, Ceylon.....	Cinnamomum zeylanicum Nees.
Cinnamon leaf, Chinese.....	Cinnamomum cassia Blume.
Cinnamon leaf, Saigon.....	Cinnamomum loureirii Nees.
Citronella.....	Cymbopogon nardus Rendle.
Citrus peels.....	Citrus spp.
Clary (clary sage).....	Salvia sclarea L.
Clove bud.....	Eugenia caryophyllata Thunb.
Clove leaf.....	Do.
Clove stem.....	Eugenia caryophyllata Thunb.
Coca (decoctified).....	Erythroxylum coca Lam. and other spp. of Erythroxylum.
Coffee.....	Coffea spp.
Cola nut.....	Cola acuminata Schott and Endl., and other spp. of Cola.
Coriander.....	Coriandrum sativum L.
Cumin (cummin).....	Cuminum cyminum L.
Cusparia bark.....	Galipea officinalis Hancock.
Dill.....	Anethum graveolens L.
Estragole (edragol, esdragon, taragon).....	Artemisia dracunculus L.
Fennel, sweet.....	Foeniculum vulgare Mill.
Penugreek.....	Trigonella foenum-graecum L.
Garlic.....	Allium sativum L.
Geranium, East Indian.....	Cymbopogon martini Stapf.
Geranium, rose.....	Pelargonium graveolens L'Her.
Ginger.....	Zingiber officinale Rosc.
Glycyrrhiza.....	Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.
Grapefruit.....	Citrus paradisi.
Guava.....	Psidium spp.
Hoarhound.....	Marrubium vulgare L.
Hops.....	Humulus lupulus L.
Jasmine.....	Jasminum officinale L. and other spp. of Jasminum.
Juniper (berries).....	Juniperus communis L.
Kola nut.....	Cola acuminata Schott and Endl., and other spp. of Cola.
Laurel leaves.....	Laurus nobilis L.
Lavender.....	Lavandula officinalis Chaix.
Lavender, spike.....	Lavandula latifolia Vill.

ESSENTIAL OILS, OLEORESINS (SOLVENT-FREE), AND NATURAL EXTRACTIVES (INCLUDING DISTILLATES)—Continued

Common name	Botanical name of plant source
Lavandin.....	Hybrids between <i>Lavandula officinalis</i> Chaix and <i>Lavandula latifolia</i> Vill.
Lemon.....	<i>Citrus Limon</i> (L.) Burm. f.
Lemon grass.....	<i>Cymbopogon citratus</i> DC. and <i>Cymbopogon flexuosus</i> Stapf.
Licorice.....	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Lime.....	<i>Citrus aurantifolia</i> Swingle.
Locust bean.....	<i>Ceratonia siliqua</i> L.
Mace.....	<i>Myristica fragrans</i> Houtt.
Mandarin.....	<i>Citrus reticulata</i> Blanco.
Marjoram, sweet.....	<i>Majorana hortensis</i> Moench.
Maté.....	<i>Ilex paraguayensis</i> St. Hil.
Mustard.....	<i>Brassica</i> spp.
Naringin.....	<i>Citrus paradisi</i> Macf.
Neroli, bigarade.....	<i>Citrus aurantium</i> L.
Nutmeg.....	<i>Myristica fragrans</i> Houtt.
Onion.....	<i>Allium cepa</i> L.
Orange, bitter, flowers.....	<i>Citrus aurantium</i> L.
Orange leaf.....	<i>Citrus sinensis</i> (L.) Osbeck.
Orange, bitter, peel.....	<i>Citrus aurantium</i> L.
Orange, sweet.....	<i>Citrus sinensis</i> (L.) Osbeck.
Origanum.....	<i>Origanum</i> spp.
Palmarosa.....	<i>Cymbopogon martini</i> Stapf.
Paprika.....	<i>Capsicum annum</i> L.
Parsley.....	<i>Petroselinum crispum</i> (Mill.) Mansf.
Pepper, black.....	<i>Piper nigrum</i> L.
Pepper, white.....	<i>Piper nigrum</i> L.
Peppermint.....	<i>Mentha piperita</i> L.
Peruvian balsam.....	<i>Myroxylon pereirae</i> Klotzsch.
Petitgrain.....	<i>Citrus aurantium</i> L.
Petitgrain lemon.....	<i>Citrus limon</i> (L.) Burm. f.
Petitgrain mandarin or tangerine.....	<i>Citrus reticulata</i> Blanco.
Pimenta.....	<i>Pimenta officinalis</i> Lindl.
Pimenta leaf.....	Do.
Pipassewa leaves.....	<i>Chimaphila umbellata</i> Nutt.
Pomegranate.....	<i>Punica granatum</i> L.
Prickly ash bark.....	<i>Xanthoxylum</i> (or <i>Zanthoxylum</i> ) <i>Americanum</i> Mill. or <i>Xanthoxylum clava-herculis</i> L.
Rose absolute.....	<i>Rosa alba</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., <i>Rosa gallica</i> L., and vars. of these spp.
Rose (otto of roses, attar of roses).....	Do.
Rose geranium.....	<i>Pelargonium graveolens</i> L'Her.
Rosemary.....	<i>Rosmarinus officinalis</i> L.
Rue.....	<i>Ruta graveolens</i> L.
Saffron.....	<i>Crocus sativus</i> L.
Sage.....	<i>Salvia officinalis</i> L.
Sage, Spanish.....	<i>Salvia lavandulaefolia</i> Vahl.
St. John's bread.....	<i>Ceratonia siliqua</i> L.
Schinus molle.....	<i>Schinus molle</i> L.
Spanish sage.....	<i>Salvia lavandulaefolia</i> Vahl.
Spearmint.....	<i>Mentha spicata</i> L.
Spike lavender.....	<i>Lavandula latifolia</i> Vill.
Tangerine.....	<i>Citrus reticulata</i> Blanco.
Tarragon.....	<i>Artemisia dracunculus</i> L.
Tea.....	<i>Thea sinensis</i> L.
Thyme.....	<i>Thymus vulgaris</i> L. and <i>Thymus syria</i> var. <i>gracilis</i> Boiss.
Thyme, white.....	Do.
Tuberose.....	<i>Pollanthes tuberosa</i> L.
Turmeric.....	<i>Curcuma longa</i> L.
Vanilla.....	<i>Vanilla planifolia</i> Andr. or <i>Vanilla tahitensis</i> J. W. Moore.
Violet leaves absolute.....	<i>Viola odorata</i> L.
Wild cherry bark.....	<i>Prunus serotina</i> Ehrh.
Ylang-ylang.....	<i>Cananga odorata</i> Hook. f. and Thoms.
Zedoary bark.....	<i>Curcuma zedoaria</i> Rosc.
(B) MISCELLANEOUS	
Common name	Derivation
Civet (sibeth, siset, sibetum).....	Civet cats, <i>Viverra civetta</i> Schreber and <i>Viverra zibetha</i> Schreber.
Cognac oil, white and green.....	Ethyl oenanthate, so-called.
Musk (Tonquin musk).....	Musk deer, <i>Moschus moschiferus</i> L.